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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,833	06/23/2000	Alex Turner	8535-036-999	9468

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EXAMINER
LI, QIAN J

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 03/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/602,833	TURNER ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 June 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The election and Preliminary Amendment filed on September 5 and October 9, 2001 have been entered and assigned as Paper Nos: 7 & 8. Claims 1-6 and 8 have been amended, claims 7 and 9-20 have been canceled, and claim 21 is newly added.

The examiner assigned to your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Q. Janice Li, at Group Art Unit 1632.

Election/Restrictions

Applicant's provisional election of Group I, claims 1-6, and 8, and the request to examine both SEQ ID Nos: 1 & 3 in Paper No. 7 is acknowledged. Because applicant has canceled the claims drawn to non-elected inventions in Paper #14, the election has been treated as an election without traverse (MPEP § 818.03(a)). Election was made **without** traverse in Paper No. 8. Please note that per applicants request, two sequences will be examined in the instant application.

Currently, claims 1-6, 8, and 21 are pending and under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 3-6, and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by *Zhao et al* (EST database).

Claims 1, 3-6 are drawn to an isolated nucleic acid molecule comprising at least 24 contiguous bases of SEQ ID Nos: 1 or 3, complement thereof; or an isolated nucleic acid molecule that hybridizes under stringent condition to SEQ ID Nos: 1 or 3; an expression vector comprising the nucleic molecule and a host cell comprising the vector.

Zhao et al disclose two nucleic acid molecules having accession numbers AQ427239 and AQ427288 in the EST database, which contain at least 24 contiguous bases of SEQ ID Nos: 1 or 3, respectively, and which share best local similarity with the recited sequences ranging from 85.2-100%, thus, could hybridize with said sequences. Because the cloning and sequencing process use vectors and host cells containing the nucleic acid, therefore, *Zhao et al* anticipate the instant claims.

Claims 1, 3-6, and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by *Carninci et al* (Methods in enzymol 1999 April;303:19-44).

Claims 1, 3-6 are drawn to an isolated nucleic acid molecule comprising at least 24 contiguous bases of SEQ ID Nos: 1 or 3, complement thereof; or an isolated nucleic acid molecule that hybridizes under stringent condition to SEQ ID Nos: 1 or 3; an

expression vector comprising the nucleic molecule and a host cell comprising the vector.

Carninci et al disclose a nucleic acid molecule having the accession number AK010252 in the EST database, which contain at least 24 contiguous bases of SEQ ID No: 1, and which share 72.8% of sequence homology and 83% of best local similarity with instant SEQ ID No: 1, thus, could hybridize with said sequence. *Carninci et al* use lamda and pBluescript vectors and host cells for cloning process, therefore, *Carninci et al* anticipate the instant claims.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, for example, lines 5 and 19 of page 14. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 101 & 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8, and 21 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The specification teaches that the present invention relates to the discovery, identification and characterization of novel human polynucleotides, referred to collectively as SGT4, which encode proteins involved in signal transduction mechanisms. The invention is based, in part, on the discovery that SGT4 shares substantial sequence homology with lucine rich repeat domain (LLRa) containing proteins, particularly RSU-1 and flightless-I protein homolog, but its primary sequence is unique. The expression of SGT4 is detected in various human tissues, and at particular high levels in skeletal muscle and heart. The specification discloses the sequences of SGT4 and variants; however, it fails to disclose the functional aspect of SGT4, its specific/particular role in the asserted signal transduction mechanism. In view that the biological role of flightness-I is still unknown (*Fong et al*, Genomics 1999;58:146-157), and in view of the fact that the primary sequence of SGT4 is unique, it is unclear what is the role of SGT4 in the signal transduction mechanism. Thus, the specific utility is not well established.

Applicant is referred to the Revised Utility Examination Guidelines published December 21, 1999 in the Federal Register, Volume 64, Number 244, pages 71441-71442 for the required *specific* and *substantial* utility. "A CLAIMED INVENTION MUST HAVE A SPECIFIC AND SUBSTANTIAL UTILITY. THIS REQUIREMENT EXCLUDES 'THROW-AWAY' 'UNSUBSTANTIAL', OR 'NONSPECIFIC' UTILITIES," (column 3, 3rd paragraph of page 71441). In the current office

practice, utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not *substantial* utilities. A claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target, or a clearly depicted chromosomal location. Similarly, a general statement of a utility for further gene discovery, such as probing an unspecified gene, detecting such gene expression in cells, making antibodies or a transgenic animal would ordinarily be insufficient in the absence of a disclosure concerning a particular gene or its disease association.

In the instant specification (pages 36-69), the disclosed utilities for the claimed polynucleotides are "used by the research community for various purposes"; "derive PCR primers", "identify chromosomes or to map related gene positions"; "identify potential genetic disorders", "provide nutritional sources or supplements", assaying and screening for compounds and proteins interacting with SGT4, making engineered cells or transgenic animals, use as diagnostic and therapeutic agent, making antisense strands and triplex probes, polypeptides and, subsequently, corresponding antibodies, etc. The disclosed utility for the claimed vectors and host cells is for the production of more polynucleotide or of polypeptides encoded thereby.

However, neither the specification nor any art of record discloses or suggests a utility for any one of the gene products, any one of the genes, cDNAs, or antisense strands which might be isolated using the claimed polynucleotide. A method of making a material does not have a specific and substantial asserted utility in those instances

where the final product, (polynucleotide for encoding a polypeptide, polypeptides, antibodies, antisense strands) has no disclosed or well-established utility.

Furthermore, these asserted utilities apply to many unrelated human polynucleotide fragments, especially in the absence of disclosure concerning tissue distribution of the corresponding mRNA and particular map location of the corresponding genes, any possible presence and distribution of polymorphism in human populations or identification of linked disease genes. Therefore the asserted utilities are not considered "specific" utilities, i.e. they are not specific to the polynucleotides claimed because no distinguishing characteristics beyond a single nucleotide sequence are disclosed.

With regard to the asserted utility for use as markers for tissues in which the corresponding protein is preferentially expressed either constitutively or at a particular stage of tissue differentiation or development or in disease states. The specification discloses (1st paragraph on page 49) that SGT4 and variants are expressed at higher levels in certain specific tissue and cell types, particularly in neuronal tissue, heart, liver, pancreas and adrenal gland (which encompassing a significant number of tissue and cell types), it fails to disclose whether other cells or tissues would also express such molecule, whether such expression is constitutive or stage-specific in the development and diseases. Since most genes are expressed in multiple tissues and cell types and some genes are expressed in all cell types, particularly if it is a protein in signal transduction pathway, the mRNAs corresponding to the claimed polynucleotide will most likely be also expressed in cells other than those disclosed in the specification. In

the absence of information regarding all possible potential expression sites of the mRNA, one cannot use the claimed polynucleotide as a marker. The specification does not teach any use for a particular tissue marker, nor has any evidence of a well-established utility for such a use been provided.

With regard to the asserted utility of a nutritional supplement, the specification fails to disclose which disease or symptom is associated with SGT4 deficiency, nor has any evidence that such supplement would correct a nutritional deficiency been provided.

In view of the instant specification, the only readily apparent *immediate* utility for the disclosed polynucleotide is characterization of the polynucleotide itself in terms of map location, possibility of association with a disease gene, sequence of corresponding mRNA, cDNA, gene and polypeptide, identity of the function for the corresponding polypeptide and variants, *etc*. The sole *immediate* utility constitutes research on the claimed product itself (which is a non-statutory utility) in order to determine a specific and substantial statutory utility for the claimed invention. Practice of these disclosed utilities would first require further research on the disclosed sequences itself, i.e. there is no apparent immediate benefit to the public. *Brenner v. Manson*, 148 USPQ 689, 696 (US SupCt., 1966), noted that "CONGRESS INTENDED THAT NO PATENT BE GRANTED ON A CHEMICAL COMPOUND WHOSE SOLE 'UTILITY' CONSISTS OF ITS POTENTIAL ROLE AS AN OBJECT OF USE-TESTING", and stated, in context of the utility requirement, that "A PATENT IS NOT A HUNTING LICENSE. IT IS NOT A REWARD FOR THE SEARCH, BUT COMPENSATION FOR ITS SUCCESSFUL CONCLUSION."

Because the claimed invention is not supported by a specific and substantially asserted utility or a well-established utility for the reasons set forth above, credibility of any utility cannot be assessed.

Claims 1, 3-6, 8, and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the Revised Interim Guidelines for "Written Description" requirement published December 21, 1999 in the Federal Register, Volume 64, Number 244, pages 71427-71440. "POSSESSION MAY BE SHOWN IN ANY NUMBER OF WAYS. POSSESSION MAY BE SHOWN BY ACTUAL REDUCTION TO PRACTICE, BY A CLEAR DEPICTION OF THE INVENTION IN DETAILED DRAWINGS...OR BY A WRITTEN DESCRIPTION OF THE INVENTION DESCRIBING SUFFICIENT RELEVANT IDENTIFYING CHARACTERISTICS SUCH THAT A PERSON SKILLED IN THE ART WOULD RECOGNIZE THAT THE INVENTOR HAD POSSESSION OF THE CLAIMED INVENTION." (page 71435, middle column, first paragraph of "a")

Claims 1, 3-6, 8, and 21 are directed to polynucleotides comprising the fragments of one of the recited sequences, complements, vectors and cells comprising these polynucleotides. Claim 1 embraces any sequence comprising at least 24 contiguous bases of SEQ ID Nos: 1 or 3, claim 3 embraces any sequence hybridizing to SEQ ID Nos: 1 or 3, therefore, these claimed polynucleotides contain sequences in addition to the recited SEQ ID NOs. In view of the breadth of the claims when given the broadest, reasonable interpretation, these claims embrace a large number of polynucleotides,

which encode a protein that may or may not function as signal transduction proteins. The specification fails to provide an adequate written disclosure for all polynucleotides encompassed by the claims and their functional characteristics, whether any sequence fragments, complements would also function as full length SEQ ID Nos: 1 or 3.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Considering the potential large numbers of polynucleotides encompassed by these claims, the disclosure is not sufficient to show that a skilled artisan would recognize that the applicants were in possession of the claimed invention commensurate to its scope at the time the application was filed.

Claims 1-6, 8, and 21 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a well established utility for the reasons set forth in the rejection under § 101 above, and since the claimed

invention does not satisfy the written description provision as set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1-6, 8, and 21 are directed to polynucleotides comprising one of the recited sequences or fragments thereof, complements, vectors and cells comprising these polynucleotides. Claim 1 embraces any sequence comprising at least 24 contiguous bases of SEQ ID Nos: 1 or 3, claim 3 embraces any sequence hybridizing to SEQ ID Nos: 1 or 3, therefore, these claimed polynucleotides contain sequences in addition to the recited SEQ ID NOs. However, the specification fails to provide an enabling disclosure for what such polynucleotides would comprise and how one would use such polynucleotides. The disclosed polynucleotides, as set forth to the recited SEQ ID NOs, represent small fragments of polynucleotides disclosed in the specification, and have not been characterized concerning their particular function and chromosomal map location.

As noted above, the specification only provides guidance for the use of the recited polynucleotides for further experimentation in the elaboration of potential proteins encoded by the claimed polynucleotides are functional in signal transduction pathway; or for the use of the claimed nucleic acids in, for example, chromosome mapping, tissue-type identification, or treating and diagnosing a disease. The first use represents an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed nucleic acids. The second use represents a function that is manifest in the polynucleotide itself and does not require, *a priori*, that the nucleic acid encode any particular product *per se*. However the invention as defined by the claims, particularly those related by hybridization performance and a 24-base contiguity characteristics, is drawn to undisclosed nucleic acids that are not required to have any particular degree of sequence identity and would not necessarily be useful for

chromosome mapping and may not necessarily encode any putative proteins that the specifically disclosed nucleic acids might encode. Therefore, the artisan would not have been able to prepare the claimed polynucleotides that are only required to same hybridization condition to those specifically disclosed, and even were such possible, the artisan would have been unable to use the invention based upon the specification as filed. Thus, given the lack of guidance and direction in regard to what the polynucleotides would comprise and how one would use such, the artisan would be required to exercise undue experimentation in practice of the invention.

The full scope of the claims is not enabled because of the large number of sequences embraced by the claims coupled with the lack of adequate guidance in the application as to which sequences to isolate or construct. The Court of Appeals for the Federal Circuit has ruled that claims that embrace a large number of species of polynucleotide sequences without proper guidance in the application as to how to make and use such polynucleotides do not meet the requirements of 35 U.S.C. § 112, first paragraph, *Amgen v. Chugai* (18 USPQ2d 1016 (Fed. Cir. 1991)).

No claim is allowed. Claim 2 appears to be free of the cited art of the record, however, it is subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Clark can be reached on 703-305-4051. The fax numbers for

the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
March 4, 2002

JAMES KETTER
PRIMARY EXAMINER